ANDA 75-829 November 30, 2001

Andrx Pharmaceuticals, Inc.
Attention: Diane Servello
U.S. Agent for Andrx Pharmaceuticals, L.L.C.
4955 Orange Drive
Fort Lauderdale, FL 33314

Dear Madam:

Reference is made to your abbreviated new drug application dated March 31, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Etodolac Extended-Release Tablets, 400 mg and 500 mg.

Reference is also made to your amendments dated October 26, 2001.

The listed drug product (RLD), Lodine® XL Extended-release Tablets of Wyeth Ayerst Laboratories, Inc. is subject to a period of patent protection which expires on April 30, 2008. Your application contains a patent certification to U.S. patent 4,966,768 under Section 505(j)(2)(A)(vii)(IV) of the Act. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of the patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph 505 (j)(2)(B)(i) is received. You have notified FDA that Andrx Pharmaceuticals, L.L.C. has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Andrx Pharmaceuticals, L.L.C. within the statutory forty-five day period.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Etodolac Extended-Release Tablets, 400 mg and 500 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Lodine® XL Extended-release

Tablets, 400 mg and 500 mg, respectively, of Wyeth Ayerst Laboratories, Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution specifications are as follows:

Dissolution testing should be conducted in _____ _____. The test product should meet the following "interim" dissolution (% dissolved) specifications:

_____

_____

_____

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement – Changes Being Effected when there are no revisions to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

Under section 505(A) of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Validation of the regulatory methods has not been completed. It is the policy of the Office not to withhold approval until the validation is complete. We acknowledge your commitment to satisfactorily resolve any deficiencies associated with the validation process that may be identified.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 75-829
Division File
FIELD COPY
HFD-610/R.West
HFD-92
HFD-210/B.Poole
HFD-330/
HFD-205/
HFD-617/R.Wu (PACT)

Endorsements:
HFD-623/N.Takiar/
HFD-623/D.Gill/
HFD-617/R.Wu/11/19/01
HFD-613/J.Barlow/
HFD-613/J.Grace/

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F/T by: gp/11/20/01

APPROVAL (PACT)